REMARKS

The Office action mailed 8 June 2006, has been received and its contents carefully noted. The pending claims, claims 4, 11, 12, 22-25, and 29-31, were rejected. By this amendment, claim 1 has been amended and claims 33 and 34 have been added. Support may be found in the specification and the claims as originally filed. Specific support may be found in Example 3 of the specification. No statutory new matter has been added. Therefore, reconsideration and entry of the claims as amended are respectfully requested.

Rejection under 35 U.S.C. 112, first paragraph

The Examiner rejected the claims under 35 U.S.C. 112, first paragraph, as lacking written description. Specifically, the Examiner deemed that the lack of any false positive hypersensitivity reaction was not supported in the specification. However, the Examiner indicated that transient urticaria of type I hypersensitivity was supported.

Applicants respectfully submit that claim 1 has been amended to indicate that the false positive reaction is of type I hypersensitivity in humans. Applicants have also added new claims 33 and 34 which contain different verbiage consistent with that suggested by the Examiner to have written description support. As claim 1, as amended, and new claims 33 and 34 are limited to transient urticaria or false positive reactions of type I hypersensitivity, the claims comply with the written description requirement.

Therefore, the rejection under 35 U.S.C. 112, first paragraph, should properly be withdrawn.

Rejection under 35 U.S.C. 102(b)

The Examiner rejected claims 4, 30 and 32 under 35 U.S.C. 102(b) as being anticipated by DOD-8B or Stitler et al. (1994 and 1995). The Examiner also rejected claims 4, 29, 30 and 32 under 35 U.S.C. 102(b) as being anticipated by Stitler et al. (1998). The Examiner indicated that Applicants arguments were not deemed to be persuasive as the claims were not limited to reactions in humans and that it has not been established that dextran does not cause under any circumstances hypersensitivity reactions in guinea pigs.

Applicants respectfully submit that the claims as amended are directed to compositions

which do not cause transient urticaria or a false positive reaction of type I hypersensitivity in a *human* subject. Again, Applicants respectfully submit that is well known in the art that animals and humans exhibit different hypersensitivities to a plurality of compounds and that the cited prior art does not teach microfluidized lysate preparations which do not cause transient urticaria or a false positive reaction of type I hypersensitivity in a *human* subject.

Therefore, the claimed invention is novel and the rejections under 35 U.S.C. 102(b) should properly be withdrawn.

Rejection under 35 U.S.C. 103(a)

The Examiner rejected claims 11, 21 and 22-25 under 35 U.S.C. 103(a) as being unpatentable over DOB-8B or Stitler et al. (1994 and 1995) or Stitler et al. (1998) in view of Reed et al.

As set forth above, none of the cited prior art references teach microfluidized lysate preparations which are (1) free of dextran and (2) does not cause transient urticaria or a false positive reaction of type I hypersensitivity (3) in a human subject.

No combination of the cited references result in a microfluidized lysate preparation which is (1) free of dextran and (2) does not cause transient urticaria or a false positive reaction of type I hypersensitivity (3) in a human subject. Thus, a prima facie case of obviousness can not be established. Further, since it is unclear as to what preparation was tested and what reaction did not result in Rowton et al. (1996) one skilled in the art would not have been motivated combine the cited references to obtain a microfluidized lystate preparation (1) free of dextran which (2) does not cause transient urticaria or a false positive reaction of type I hypersensitivity (3) in a human subject with a reasonable likelihood of success.

Therefore, the claimed invention is unobvious and the rejection under 35 U.S.C. 103(a) should properly be withdrawn.

Request for Interview

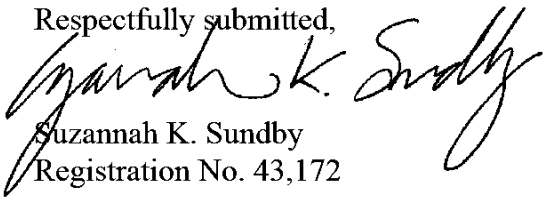
Applicants respectfully request either a telephonic or an in-person interview should there be any remaining issues.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefor are hereby authorized to be charged to **Deposit Account No. 210-380,** Attorney Docket No. **034047.013 (WRAIR 98-40/98-46)**.

Respectfully submitted,



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